K030624

MAR 17 2004

SUMMARY OF SAFETY AND EFFECTIVENESS DATA RELATING TO SUBSTANTIAL EQUIVALENCE

Proprietary Name:	Fabius GS Anesthesia System
Classification Name:	Gas Machine, Anesthesia – 73 BSZ
Device Class:	Class II
Initial Distributor:	Draeger Medical, Inc. 3135 Quarry Road Telford, Pennsylvania 18969 USA
Establishment Registration No.:	2517967
Devices to which substantial equivalence is claimed:	Fabius GS Anesthesia System – K011404 Evita 4 Continuous Ventilator – K961687

Device Description:

The modified Fabius GS is a continuous flow gas anesthesia system.

Intended Use:

The modified Fabius GS may be used for spontaneous, manually assisted, automatic, or pressure support ventilation of patients during anesthesia, and delivery of gases and anesthetic vapor. The modified Fabius GS can monitor inspired oxygen concentration, breathing pressure, and respiratory volume.

Substantial Equivalence:

The current Fabius GS Anesthesia System (K011404) is being modified to include Pressure Support Ventilation as an optional ventilation mode. The addition of Pressure Support Ventilation is essentially a software change. The only hardware change was the addition of the Pressure Support hard key on the operator control panel. With the exception of minor incremental changes that did not require a 510(k) notification, the basic infrastructure, operating principle, alarm strategies, fault detection circuitry, and mechanical/pneumatic subassemblies within the Fabius GS remain unchanged from the initially released Fabius GS. Adjustable ventilation settings available in Pressure Support mode are Support Pressure Level, Trigger Level (sensitivity level at which a breath is detected), Maximum Inspiratory Flow, and Positive End Expiratory Pressure. Support Pressure Level and Trigger Level are new settings. Maximum Inspiratory Flow and Positive End Expiratory Pressure are ventilation settings already available to the user in the current automatic ventilation modes.

Like the Evita 4 Continuous Ventilator (K961687), Pressure Support Ventilation (PSV) in the Fabius GS is flow triggered and flow cycled.

Qualification of the modified Fabius GS included hazard analysis, system level qualification, and verification/validation tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2004

Mr. Michael A. Kelhart
Regulatory Affairs Project Manager
Draeger Medical Incorporated
3135 Quarry Road
Telford, PA 18969

Re: K030624
Trade/Device Name: Fabius GS Anesthesia System
Regulation Number: 868.5160
Regulation Name: Gas Machine, Anesthesia
Regulatory Class: II
Product Code: BSZ
Dated: February 18, 2004
Received: February 19, 2004

Dear Mr. Kelhart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030624

Device Name: Fabius GS Anesthesia System

Indications for Use:

The Fabius GS is indicated as a continuous flow anesthesia system. The Fabius GS can be used for spontaneous, manually assisted, automatic or pressure support ventilation, delivery of gases and anesthetic vapor, and monitoring oxygen concentration, breathing pressure and respiratory volume of patients during anesthesia. Federal law restricts this device to sale by or on the order of a physician.

Prescription Use √ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030624